PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7:

(11) International Publication Number:

WO 00/51668

A61M 5/00

A1

(43) International Publication Date:

8 September 2000 (08.09.00)

(21) International Application Number:

PCT/US00/05640

(22) International Filing Date:

3 March 2000 (03.03.00)

(30) Priority Data:

60/123,305

5 March 1999 (05.03.99)

US

(71) Applicant (for all designated States except US): ACCUMED SYSTEMS, INC. [US/US]; 334 E. Washington, Ann Arbor, MI 48104-2010 (US).

(72) Inventor; and

(75) Inventor/Applicant (for US only): KOROTKO, Joseph, R. [US/US]; 2234 Hillcrescent, Troy, MI 48098 (US).

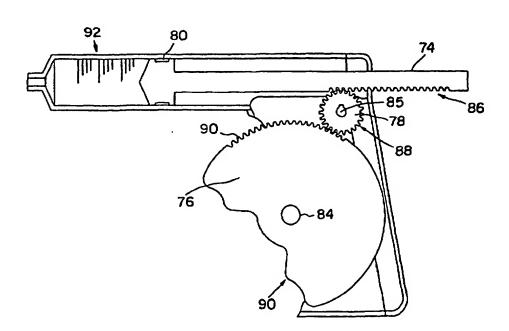
(74) Agent: SOLOWAY, Norman, P.; Hayes, Soloway, Hennessey, Grossman & Hage, P.C., 175 Canal Street, Manchester, NH 03101 (US). (81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CJ, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: HIGH PRESSURE SYRINGE



(57) Abstract

A high pressure syringe comprises in combination a barrel (70) having a hand gun-like handle (72), a plunger (74) slidably mounted within the barrel, and a disc trigger (76) rotatably mounted on the handle, said disc trigger having a plurality of teeth (90) on a peripheral edge thereof, for interfacing via an interposed toothed wheel (78) with gear teeth (86) on a stem of the plunger.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

L	Albania	ES	Spain	LS	Lesotho	SI	Stovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ.	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Tago
BB	Barbados	CH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav	TM	Turkmenistan
BF	Burkina Faso	GR	Greece		Republic of Macedonia	TTR	Turkey
BC	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	12	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	υG	Uganda
BY	Belarus	18	Iceland	MW	Malawi	us	United States of America
CA	Canada	IT	Italy	MX	Mexico	U2	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	zw	Zimhabwe
Cī	Côte d'Ivoire	KP	Democratic People's	NZ	New Zealand		
CM	Cameroon		Republic of Korea	PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	K2	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	L	Licchtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SC	Singapore		

1	HIGH PRESSURE SYRINGE				
2	The present invention is directed to syringes. The invention has				
3	particular utility for injecting viscous materials into a manifold, needle,				
4	catheter or the like; for example, the very viscous dye required to visualize				
5	coronary anatomy in diagnosis and treatment of arterial diseases, and will be				
6	described in connection with such utility, although other utilities are				
7	contemplated.				
8	Currently available syringes require the exertion of a tremendous				
9	amount of hand pressure, often resulting in suboptimal injections and hand				
10	fatigue. Most syringes used for this purpose involve two loops on opposite				
11	sides of the syringe for the first and second fingers and a plunger which eithe				
12	fits in the palm of the hand or is operated by the thumb. Such syringes are				
13	marketed by NAMIC, MERIT, Statco, Fruend, the ACS division of Eli Lilly				
14	and other medical device manufacturers. Recently, cardiovascular				
15	innovations introduced a high pressure syringe illustrated in Fig. 1 in which a				
16	syringe 30 is mounted in a frame 32 comprising a base 34 and a pivotally				
17	mounted lever arm 36 which provides a mechanical advantage for operating				
18	the syringe 30.				
19	Yet another high pressure syringe is shown in U.S. Patent 5,078,690.				
20	Referring to Figs. 2 and 3 which are assembly drawings from U.S. Patent				
21	5,078,690, the syringe comprises an outer housing portion generally indicated				
22	at 2, and an inner portion generally indicated at 4. The outer portion 2				
23	preferably is formed of an optically transparent material, and has a				
24	downwardly extending finger grip handle 6 which is shown to be open at the				
25	rear 7. The inner housing has a downwardly extending inner handle 8 which				
26	fits within the opening 7. The upper part of the outer housing 2 defines an				
27	inner cylinder 10 in which a piston 12, carried by the inner housing 4 can fit.				
28	Outer housing portion 2 and inner portion 4 each preferably comprise unitary				
29	molded parts formed of a medically approved material such as polycarbonate				

or polypropylene. A resiliently deformable sealing tip 14, formed of a

30

1	medical grade rubber, elastomer or the like, or an O-ring is carried on the
2	forward end 24 of piston 12 and provides a high pressure seal between the
3	piston 12 and the inner cylinder 10. A fluid feed opening 16 is provided in
4	outer housing 2 to permit egress of the high pressure viscous liquid into a
5	suitably attached catheter, manifold, needle or the like.
6	The catheter or other injection system device is attached with a female
7	coupling known in the trade as a LUER-LOK to the outer housing male
8	LUER-LOK tip 22. An alternative embodiment utilizes a captive and rotatable
9	female threaded fitting with an O-ring seal affixed to the syringe tip 22. Both
10	embodiments incorporate rotatable couplings that are snapped together.
11	The present invention provides an improvement in high pressure
12	syringes. More particularly, in accordance with the present invention, there is
13	provided a hand gun-like shape syringe having a barrel with a handle. A
14	plunger is mounted within the barrel. A disc trigger is rotatably mounted on
15	the handle, and has a plurality of teeth on a peripheral edge thereof for
16	interfacing with gear teeth on a stem of the plunger. In a preferred
17	embodiment, a gear wheel is interposed between the rotatably mounted disc
18	trigger and the stem of the plunger for providing further enhanced
19	mechanical advantage.
20	Other features and advantages of the present invention will be seen
21	from the following detailed description, taken in conjunction with the
22	accompanying drawings, wherein:
23	Figs. 1-3 are side elevational views of prior art high pressure syringe
24	devices;
25	Figs. 4 and 5 are cross-sectional views of a syringe made in a first
26	embodiment of the invention; and
27	Fig. 6 is a side-elevational view; and
28	Figs. 7 - 10 are cross-sectional views of two alternative embodiments of
29	syringes made in accordance with the present invention.

1 Referring to Figs. 4 and 5, the syringe in accordance with a first 2 embodiment of the present invention has three main components, a barrel 40 with a handle 42, a slidably mounted plunger 44, and a rotatably mounted 3 4 disc trigger. In addition to these elements, the syringe also has other 5 necessary or miscellaneous components, such as a seal 50 on the plunger and 6 a disc trigger pivot pin 54. The barrel with handle is similar to other syringe 7 designs such as U.S. Patent No. 5,078,690 that have a hand gun-like shape. 8 The plunger 44 is slidably mounted within the barrel 40, and has gear teeth 9 56 which interface with teeth 58 of the disc trigger 46. The disc trigger 46 10 rotates about pivot pin 54 at its center and is used to move the plunger 44. 11 The disc trigger and plunger work together like a rack-and-pinion gear works. 12 When the upper portion 60 of the disc trigger 46 of the disc trigger is 13 squeezed, it causes the plunger to move backward in the barrel thus filling the 14 syringe with fluid. (See Fig. 4). Conversely, when the lower portion 62 of the 15 disc trigger is squeezed, it causes the plunger to move forward and thus 16 injecting the fluid into the catheter system. (See Fig. 5). 17 An alternative embodiment of syringe in accordance with the present 18 invention is shown in Fig. 6-8. 19 Referring to Figs. 6-8, the syringe includes a barrel 70 with a handle 72, 20 a slibably mounted plunger 74, a rotatably mounted disc trigger 76 and gear 21 wheel 78. In addition to these, the syringe also has other necessary or 22 miscellaneous components, such as a seal 80 on the plunger and pivot pins 84, 23 85. As before, the barrel with handle is similar to other syringe designs such 24 as U.S. Patent No. 5,078,690 that have a hand gun-like shape. The plunger 74 25 is slidably mounted in the barrel, and has gear teeth 86 which interface with 26 teeth 88 of the gear wheel 78. The gear wheel 78 is rotatably mounted and 27 positioned between the plunger 74 and disc trigger 76, and is contained 28 within the handle 72. The disc trigger 76 turns about pivot pin 84 at its center 29 and is used to rotate gear wheel 78 by interface of teeth 90 with teeth 88 of

1 gear wheel 78 which in turn moves the plunger 74. The disc trigger, gear 2 wheel, and plunger all work together like a rack-and-pinion gear works. When the lower portion 90 of the disc trigger 76 of the disc trigger is 3 4 squeezed, it causes the plunger to move backward in the barrel thus filling the syringe with fluid. (See Fig. 7). Conversely, when the upper portion 92 of the 5 disc trigger is squeezed, it causes the plunger to move forward in the barrel, 6 7 thus injecting fluid in the barrel into the catheter system. (See Fig. 8). 8 A further alternative embodiment of syringe in accordance with the 9 present invention is shown in Figs. 9 and 10. 10 Referring to Figs. 9 and 10, the syringe includes a barrel 100 with a 11 handle 101, a slidably mounted plunger 102, a rotatably mounted double disc trigger 103 and gear wheel 104. In addition to these, the syringe also has other 12 13 necessary or miscellaneous components, such as a seal 105 on the plunger and 14 pivot pins 106, 107. As before, the barrel handle is similar to other syringe 15 designs such as U.S. Patent No. 5,078,690 that have a gun-like shape. The 16 plunger 102 is slidably mounted in the barrel, and has gear teeth 108 which 17 interface with teeth 109 of the gear wheel 104. The gear wheel 104 is rotatably 18 mounted and positioned between the plunger 102 and double disc trigger 19 103, and is contained within handle 101. The double disc trigger 103 turns 20 about pivot pin 106 at its center and is used to rotate gear wheel 104 by interface of teeth 110 with teeth 109 of gear wheel 104 which in turn moves 21 22 the plunger 102. The double disc trigger, gear wheel, and plunger all work 23 together like a rack-and-pinion gear works. When the lower portion 111 of 24 the double disc trigger 103 is squeezed, it causes the plunger to move 25 backward in the barrel thus filling the syringe with fluid. (Fig. 9). 26 Conversely, when the upper portion 112 of the double disc trigger is

squeezed, it causes the plunger to move forward in the barrel, thus injecting

embodiment shown in Figs. 6-8. In this latter embodiment, the double disc

fluid in the barrel into the catheter system (Fig. 10), i.e. similar to the

27

28

29

trigger 103 provides additional mechanical advantage over that of the 1 2 embodiment of Figs. 6-8. As force is applied to the outer disc edge 113 of the 3 double disc trigger, it yields a higher force on the inner disc edge 114. The increase in force is a ratio of the diameters of the edges of the disc. Thus, if an 4 operator can apply X-pounds of force to the outer disc edge, a force of greater 5 than X-pounds will be applied to the inner disc edge and in-turn a force of 6 greater than X-pounds will be applied to the plunger. Finger ring syringes 7 8 can only produce X-pounds of force on the plunger. 9 The aforementioned syringes have a handle mounted to the barrel that 10 has a gun-like appearance. It is conceived within the present invention that 11 the shape of the handle and barrel could be different. It is possible that the handle and barrel can be aligned to each other as opposed to nearly 12 perpendicular. In this alignment, it is still possible to have the rack-and-13 14 pinion gear mechanisms described above in order to control in-and-out 15 movement of the plunger via rotation of the disc trigger. It is also possible to 16 design the trigger in a manner that does not rotate, but still drives a disc with 17 gear teeth and thus controls in-and-out movement of a plunger. 18 The syringe of the present invention comfortably fits in the hand and it 19 uses the natural kinematics and grip strength of the hand. This strength is 20 definitely optimized when filling the syringe. Finger ring syringe designs require spreading the thumb away from the forefinger and middle finger in 21 22 order to fill the syringe. The design of the present syringe uses a squeezing 23 (or grip) action to fill and empty the syringe. The syringe design also 24 provides mechanical advantage because of the rack-and-pinion gear works, 25 particularly the Figs. 6-10 embodiments. 26 The syringe design of the present invention also has other performance

• Design that maximizes strength of hand.

include, but are not limited to the following:

27 28

29

requirements that are expected of syringes for this type of application. They

1	•	Disposal and provided sterile.
2	•	Inexpensive - the barrel and handle may be molded as a one-piece
3		unit.
4	•	Easy to use.
5	•	Volume of syringe = 15 cc or greater.
6	•	Minimum pressure threshold of 20 atm without leakage.
7	•	Force required to fill syringe or inject solution not to exceed force
8		requirements of current available syringes
9	•	Lucent, translucent, or see-through components as needed to
10		visualize solutions and/or a suitably marked graduated scale 92.
11	•	Fast; able to fill or inject syringe fast when needed, for example,
12		when priming the manifold, catheter, or tubing.
13	•	Low tendency for air bubbles, no more than current available
14		syringes.
15	•	Comply with mandatory or voluntary performance standards.
16	•	All materials meet biocompatibility requirements.
17		
18		

1	•	<u>CLAIMS</u>			
2	1.	A high pressure syringe, comprising, in combination:			
3	a bar	rel 70 having a handle 72;			
4	a plu	nger 74 slidably mounted within the barrel; and			
5	a dis	c trigger 76 rotatably mounted on the handle, said disc trigger			
6	having a plu	urality of teeth 90 on a peripheral edge thereof, for interfacing with			
7	gear teeth 8	6 on a stem of the plunger.			
8	2.	A high pressure syringe according to claim 1, wherein said			
9	barrel 70 an	d handle 72 comprise a one-piece molded member having a hand-			
10	gun like sha	pe.			
11	3.	A high pressure syringe of claim 1, wherein said plunger 74 is			
12	slidably sealed within said barrel.				
13	4.	A high pressure syringe according to claim 1, and further			
14	including a	rotatably mounted gear wheel 78 interposed between the			
15	rotatably m	ounted disc trigger 76 and the stem of the plunger 74.			
16	5.	A high pressure syringe according to claim 1, wherein said disc			
17	trigger 76 co	omprises a gripping surface of size and shape to accommodate			
18	multiple hu	man fingers.			
19	6.	A high pressure syringe according to claim 1, wherein said			
20	barrel is luc	ent or translucent, and includes a graduated scale 92.			
21	.7.	A high pressure syringe, comprising a barrel 100, having a			
22	handle 101,	a plunger 102 slidably mounted within the barrel, a gear wheel			
23	104, and a d	ouble disc trigger 103 rotatably mounted in the handle, said			
24	double disc	trigger having a plurality of teeth 110 on a peripheral edge			
25	thereof, for	interfacing with gear teeth 109 on said gear wheel 104 which in			
26	turn interfer	re with gear teeth 108 on a stem of the plunger; said double disc			
27	trigger havi	ng a ratio between the two discs of the trigger so that the trigger			
28	103, a gear v	wheel 104, and plunger 102 have an increased mechanical			
29	advantage b	between force input on the trigger and force output on the plunger.			

1	8. A high pressure syringe, comprising a barrel 100 having a
2	handle 101, a plunger 102 slidably mounted within the barrel, and a gear train
3	arrangement 108, 109, 110 with triggering feature 103 thereof, so that the gear
4	train controls movement of the plunger through the trigger feature.
5	9. A high pressure syringe according to claim 8, wherein said gear

9. A high pressure syringe according to claim 8, wherein said gear train arrangement 108, 109, 110 affords mechanical advantage between force 6 input on the trigger feature 103 and force output on the plunger 102.

8

7

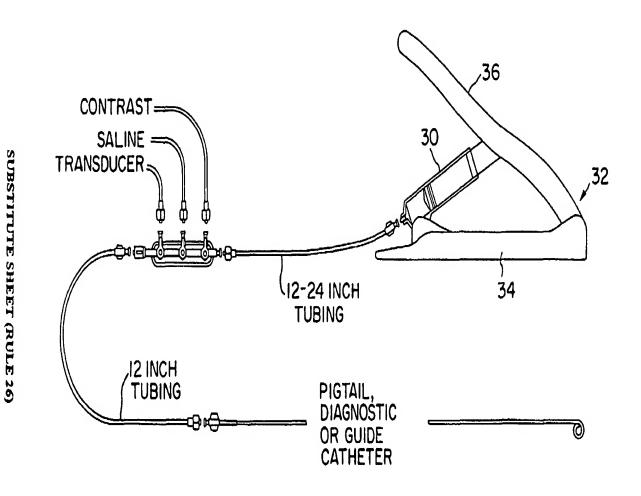


FIG. I PRIOR ART

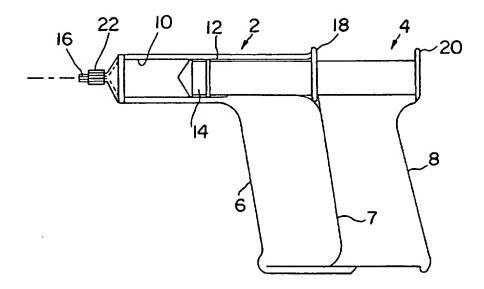


FIG. 2 PRIOR ART

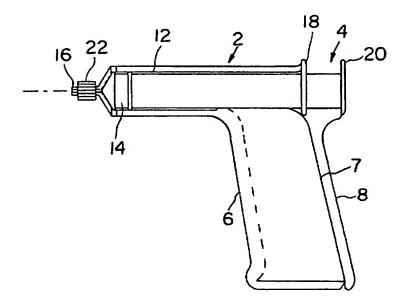


FIG. 3 PRIOR ART

SUBSTITUTE SHEET (RULE 26)

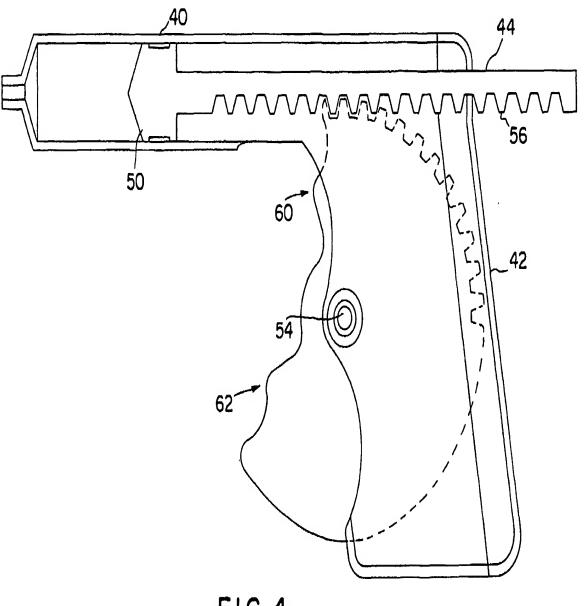
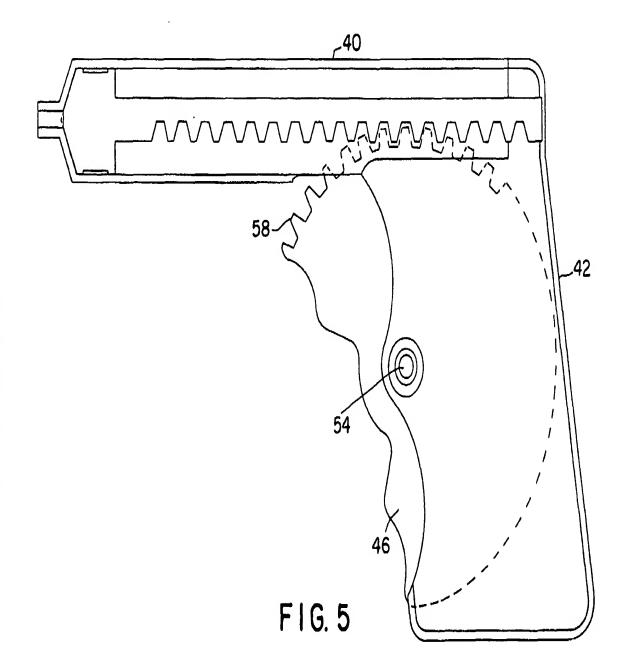


FIG. 4



SUBSTITUTE SHEET (RULE 26)

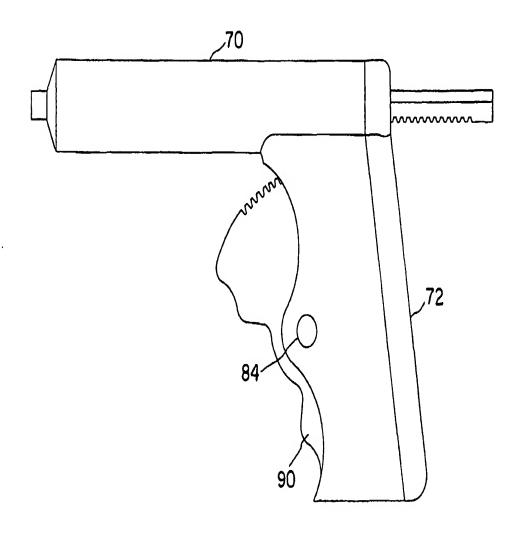


FIG. 6

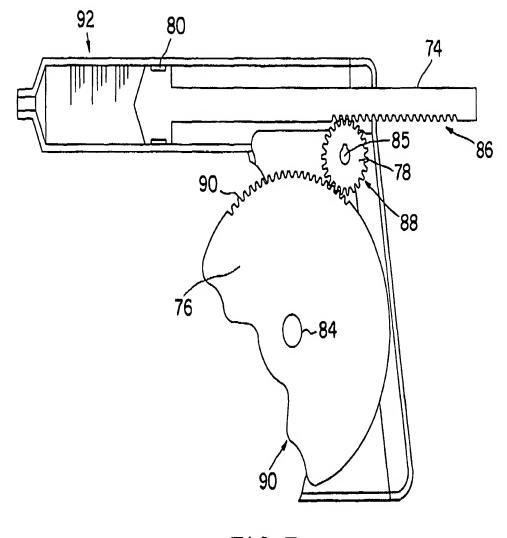


FIG. 7



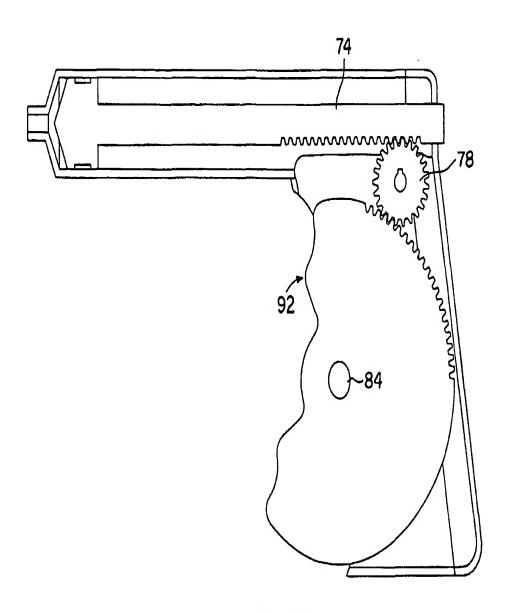


FIG.8

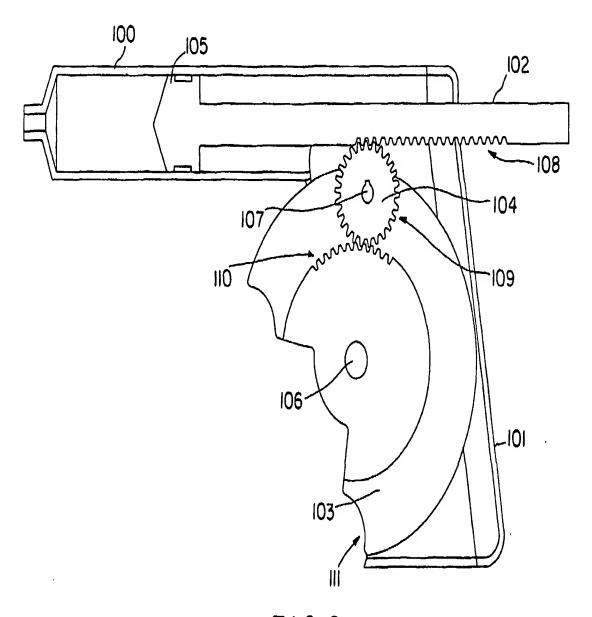
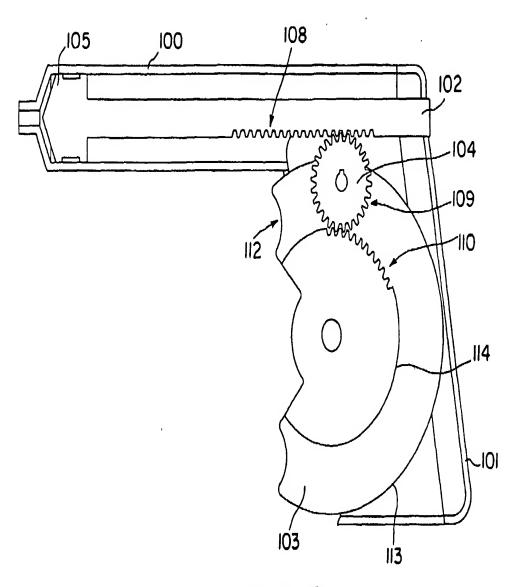


FIG. 9



F1G.10

INTERNATIONAL SEARCH REPORT

International application No. PCT/US00/05640

A. CLASSIFICATION OF SUBJECT MATTER IPC(7) :A61M 5/00 US CL :604/187 According to International Patent Classification (IPC) or to both national classification and IPC					
	.DS SEARCHED				
Minimum c	locumentation searched (classification system followe	d by classification symbols)			
	604/187,		_		
Documenta	ion searched other than minimum documentation to th	e extent that such documents are included	in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)					
C. DOC	UMENTS CONSIDERED TO BE RELEVANT				
Category*	Citation of document, with indication, where ap	propriate, of the relevant passages	Relevant to claim No.		
A	US 5,865,811 A [DOYING, SR. et al	.] 02 February 1999.	1-9		
A	US 5,785,680 A [NIEZINK et al.] 28	July 1998, entire document.	1-9		
A	US 5,078,690 A [RYAN] 07 January	1-9			
A	US 4,968,303 A [CLARKE et al.] document.	1-9			
A	US 4,883,101 A [STRONG] 28 Novem	mber 1989, entire document.	1-9		
A	US 4,014,331 A [HEAD) 29 March 1	1-9			
Further documents are listed in the continuation of Box C. See patent family annex.					
* Special categories of cited documents: "T" later document published after the international filing date and not in conflict with the application but cited to und principle or theory underlying the invention to be of particular relevance.					
	rlier document published on or after the international filing date	"X" document of panicular relevance; the			
ÇİI	ecument which may throw doubts on priority claim(s) or which is sed to establish the publication date of another citation or other ecial reason (as specified)	when the document is taken alone "Y" document of particular relevance; th	e claimed invention cannot be		
	cument referring to an oral disclosure, use, exhibition or other means	combined with one or more other suc-	h documents, such combination		
	cument published prior to the international filing date but later than e priority date claimed	•	being obvious to a person skilled in the art document member of the same patent family		
Date of the	actual completion of the international search	Date of mailing of the international sea	arch report ·		
17 MAY	2000	0 7 JUL 2000			
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT CATHERINE SERKE			Colon		
Washington Facsimile N	n, D.C. 20231 Io. (703) 305-3230	Telephone No. (703) 308-4846			
		1			

Form PCT/ISA/210 (second sheet) (July 1998)+